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February 22, 2023

VIA ECOURTS

Honorable Valerie Figueredo, U.S.M.J.
United States District Court
Southern District of New York
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: *Gref v. American Int'l Indus., Inc., et al.*
No. 1:20-cv-5589-GBD-VF

Dear Judge Figueredo:

We represent non-party Dr. Jacqueline Moline ("Dr. Moline") and respectfully submit this letter in further support of Northwell Health, Inc.'s ("Northwell") motion to modify the subpoenas served on it by Defendants American International Industries, Inc. ("AII") and Whittaker, Clark & Daniels, Inc. ("WCD") (collectively, the "Subpoenaing Defendants") pursuant to Rule 45(d)(3) of the Federal Rules of Civil Procedure.

Beyond joining in the persuasive arguments in Northwell's supplemental submission, Dr. Moline writes separately to explain the importance of research-subject anonymity and the devastating consequences that would flow from a court order compelling Northwell to identify her research subjects. As a medical researcher, Dr. Moline has a sacred professional and ethical obligation to keep personally-identifying information she compiles about her research subjects confidential. Whether the product of her research may be available from other sources in no way diminishes her obligation to ensure that it remains confidential. That point was underemphasized if not lost altogether in the Court's extended colloquy with counsel on February 8th, but it is outcome determinative here. The Common Rule, HIPAA, the IRB process, and journal editorial polies all require—and all proceed from the premise—that a medical researcher will not identify her subjects or permit them to be identified. Departing from that bedrock principle would make it impossible to secure approval to conduct and publish such research because there would no longer be an expectation that its subjects' anonymity would be preserved. This burden far outweighs any purported benefit of requiring Northwell to comply with the Subpoenas. It really is that simple.

Background

The Journal of Occupational and Environmental Medicine ("JOEM") is the official journal of the American College of Occupational and Environmental Medicine. ("ACOEM"). The JOEM is a guide for physicians, nurses, and researchers and provides "clinically oriented research articles and technical reports [to] keep occupational and environmental medicine specialists up-to-date on

new medical developments in the prevention, diagnosis, and rehabilitation of environmentally induced conditions and work-related injuries and illnesses." *See* https://journals.lww.com/joem/pages/aboutthejournal.aspx.[1] The ACOEM is "the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education." https://acoem.org/About-ACOEM/Background. JOEM states that it "adheres to the ethical policies put forth by the Committee on Publication Ethics (COPE) and the International Committee on Medical Journal Editors (ICMJE)." https://journals.lww.com/joem/Pages/editoriallegalethicalpolicies.aspx. Institutional Review Board approval and patient consent (or an exemption) are requirements for publication in JOEM. (*Id.*)

JOEM published an article authored by Jacqueline Moline, MD, MSc, Kristin Bevilacqua, MPH, Maya Alexandri, JD, and Ronald E. Gordon, PhD, entitled *Mesothelioma Associated With The Use Of Cosmetic Talc*, 62 J. Occ. & Envtl. Med. 11 (Jan. 2020) (the "Article"). (ECF No. 265-1, p8, Ex.1.) Dr. Moline was the lead author of this peer-reviewed Original Article.[2] (*Id.*) No outside source obtained any funds or external assistance in the development, writing, analysis, or conclusions of the Article. (*Id.*, bottom left.) The Article reported on a study that analyzed medical records and deposition transcripts of 33 anonymous individuals diagnosed with mesothelioma (the "Study"). (*Id.*, Case Histories.) "In some cases, individuals were also interviewed in person, and these data were merged with the data obtained in medical records and deposition transcripts." (*Id.*) Indeed, Dr. Moline testified that she obtained information from in-person interviews of the subjects if she had the opportunity to meet them. (279-7, p7, 31:12-17.) She conducted five such interviews. In addition to deposition transcripts and interviews, the Study also considered biospecimens from six research subjects, whose cases were presented in greater detail in the Article. (ECF No. 265-1, p9, Ex.1, Case Histories.)

The Study provided "the first large case series to identify cosmetic talcum powder contaminated with asbestos as the cause of malignant mesothelioma in cosmetic talc users." (ECF No. 265-1, p11, Discussion.) Dr. Moline's motivation for the Study was to raise physicians' awareness of the risks of exposure to cosmetic talc and to alert them to the need to take a comprehensive exposure history. (ECF No. 265-1, p13 (stating that "the elicitation of a history of [asbestos-contaminated talcum powder] usage is imperative to obtaining a full exposure history in all patients presenting with mesothelioma"); ECF No. 263-11, p5) ("If doctors aren't aware [of] asbestos contaminated talcum powder, they don't ask about its use, nor consider it as a source.").

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[1] The Court may take judicial notice of the description of the JOEM provided on its website. *See Jallow v. Airbnb, Inc.*, No. 20-CV-4089 (MKB), 2020 U.S. Dist. LEXIS 257343, at *1 n.1 (E.D.N.Y. Dec. 16, 2020); *Vlahos v. Schroeffel*, No. 02-cv-0139, 2006 U.S. Dist. LEXIS 95814, at *17 (E.D.N.Y. Mar. 6, 2006).

[2] During oral argument, counsel for AII asserted that "there's no evidence that this article was peer reviewed." (02/08/2023 Tr. at 117-18.) That is not correct. JOEM designated the Article an "Original Article." (ECF No. 265-1, p8, Ex.1, Header.) All Original Article manuscripts published by JOEM are "fully peer-reviewed." https://edmgr.ovid.com/joem/accounts/ifauth.pdf.

The Study "was conducted with approval from the Northwell Health Feinstein Institute for Medical Research (#18-0225 FIMR)." (ECF No. 265-1, p11, Background.)

The Subpoenaing Defendants seek a spreadsheet that discloses the identities of the subjects of the Study. (2/8/2023 Tr. at 104:18-23, 110:4-8.) The identity of one of the subjects, Betty Whitley Bell, was disclosed in another litigation. *Bell v. Am. Int'l Indus.*, No. 17-cv-0111, __ F. Supp. 3d __, 2022 U.S. Dist. LEXIS 199180 (M.D.N.C. Sep. 13, 2022). Defendants acknowledge that Brian Gref, the plaintiff in this case, is not one of the subjects of the Study. (2/8/2023 Tr. at 6:2-4.) Dr. Moline has complied with her ethical and legal obligations in retaining the anonymity of the subjects of the Study. (*Id.* at 31:15-19.)

Legal Standard

Rule 45(d)(3) requires the Court to quash or modify a subpoena that requires "disclosure of privileged or other protected matter" or "subjects a person to undue burden." Fed. R. Civ. P. 45(d)(3)(A)(iii), (iv).

On a motion to quash, the party issuing the subpoena has the initial burden of demonstrating that "the information sought is relevant and material to the allegations and claims at issue in the proceedings." *Shaw v. Arena*, No. 17-mc-0448-AJN, 2018 U.S. Dist. LEXIS 2308, at *3 (S.D.N.Y. Jan. 3. 2018) (cleaned up). A subpoena that seeks "material with little apparent or likely relevance to the subject matter is likely to be quashed as unreasonable even where the burden of compliance would not be onerous." *Id.* (cleaned up).

If and when relevance is established, the movant bears the burden of demonstrating privilege or undue burden. *Id.* In determining whether a subpoena imposes an undue burden, the court must "balance the interests served by demanding compliance with the subpoena against the interests furthered by quashing it, which calls upon the trial court to consider whether the information is necessary and whether it is available from any other source." *Id.* at *4 (cleaned up). To demonstrate undue burden, the movant must explain "the manner and extent of the burden and the probable negative consequences of insisting on compliance." *Id.* (cleaned up).

Argument

I. The Subpoenaing Defendants Have Not Sustained Their Burden To Establish That The Spreadsheet Is Relevant And Material To Any Of The Claims Or Allegations In The Underlying Proceeding

The Subpoenaing Defendants have not demonstrated that the spreadsheet revealing the identities of the subjects of the Study is relevant to any of the claims in the underlying proceeding. Indeed, Plaintiff is not even one of the subjects of the Study. (2/8/2023 Tr. at 6:2-4.) In her Expert Report, Dr. Moline relied on 492 references to support her conclusions and only briefly mentioned the Article. (ECF No. 282-16, pp57-83, p72, No.304. p22, top & n.2.) Consideration of similar facts led Judge Miller in the Eastern District of Virginia to conclude that information of the type AII seeks is "minimally relevant" to its defense in this action. (ECF No. 306-1, p6.) Given the

minimal apparent relevance the subpoenaed information has to the underlying dispute, the Court should quash the subpoenas as unreasonable. *See Shaw*, 2018 U.S. Dist. LEXIS 2308, at *3.

AII nevertheless asserts that "concealing the identities of these subjects and their alternative exposures significantly hamstrings A-I-I's cross-examination of Dr. Moline, and it creates an obvious Daubert issue in that A-I-I cannot determine whether her opinions are based on "sufficient facts or data" and "reliable principles." (ECF No. 279, p27.) In other words, unlike in *Bell*, the Subpoenaing Defendants have all but conceded that the information they seek has no direct bearing on the case. Instead, they want to know the identities of the subjects because they want to investigate them and their family members[3] in an effort to undermine the Article's conclusion that "mesothelioma cases once considered idiopathic may be attributable to asbestos-contaminated powder usage." (ECF No. 265-1, p13.) If proven, the fact that some of the subjects may have had other asbestos exposures might call into question—but would not contradict—the Article's conclusion that mesothelioma "***may*** be attributable" to contaminated powder usage. That possibility hardly justifies Defendants' planned fishing expedition. It is a well-established rule in the Second Circuit that "the parties should not be permitted to roam in shadow zones of relevancy and to explore matter which does not presently appear germane on the theory that it might conceivably become so." *Lemanik v. McKinley Allsopp, Inc.*, 125 F.R.D. 602, 608 (S.D.N.Y. 1989) (cleaned up).

Because the Subpoenaing Defendants have failed to carry their initial burden of proving the relevance of the spreadsheet, the Court should quash their Subpoenas.

II. Dr. Moline's Interests In Preserving The Anonymity Of The Subjects Far Outweigh Any Need On The Part Of The Subpoenaing Defendants For The Spreadsheet

"A general, fundamental tenet of much modern academic human-centered research . . . is a guarantee of confidentiality for respondents." Eric Robinson, *No Confidence: Confidentiality, Ethics and the Law of Academic Privilege*, 21 Comm. L. & Pol'y 323, 327-28 (Summer 2016). As a researcher of human subjects, Dr. Moline has an ethical obligation to protect the identities of her research subjects. *See* Emily Haney-Caron, *et al.*, *Safe from Subpoena? The Importance of Certificates of Confidentiality to the Viability and Ethics of Research*, 48 Akron L. Rev. 349, 351 (2019).

Dr. Moline also has a legal obligation to protect her subjects' identity, even if her use of their private information or biospecimens was not the subject of express consent. The Common Rule requires that "[w]hen appropriate," there must be "adequate provisions to protect the privacy

[3] The Article makes clear that talcum-powder-exposure histories were based in part on sworn testimony of family members with first-hand knowledge of the subject's use of talcum powder. (ECF No. 265-1, p9.)

of subjects and to maintain the confidentiality of data." 45 C.F.R. § 46.111(a)(7).[4] In cases in which an investigator uses secondary research (such as using deposition transcripts to glean exposure history), the Common Rule requires the investigator to record the information, including information about biospecimens, "in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subject." 45 C.F.R. § 46.104(d)(4)(ii). Moreover, the investigator may "not re-identify subjects." *Id.* Should Dr. Moline violate these regulations, even under subpoena, there might well be an attempt to hold Northwell responsible. Robinson, 21 Comm. L. & Pol'y at 328 n.24. The sanction for non-compliance with the regulation is loss of federal funding. *Id.*

In addition to the Common Rule, Dr. Moline must comply with the Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule"). CFR parts 160, 164. The Privacy Rule prohibits the disclosure of "protected health information" ("PHI") except as expressly permitted by the rule. 45 C.F.R. § 164.502. For purposes of the Privacy Rule, PHI means "individually identifiable health information," which includes names. 45 C.F.R. §§ 160.103, 164.514(b)(2)(i)(A).[5] Here, Defendants intend to use such information in an attempt to undermine the Article's conclusions and attack Dr. Moline's credibility in this and other proceedings. (ECF No. 279, p27) ("Northwell asks this Court to aid it in continuing to mislead the medical community, judges, and jurors into believing that this Article shows a link between cosmetic talc and mesothelioma, when the underlying facts show this to be false."); *Bell*, 2022 U.S. Dist. LEXIS 199180, at *16 ("AII seeks to vacate the protective order so the Northwell Document can be used in other litigation."). That would undermine HIPAA's requirement that even where a court orders disclosure of PHI in a particular litigation, its use must be limited to that litigation. 45 C.F.R. § 164.512(e)(1)(v)(A).

Moreover, compliance with the subpoenas would interfere with Dr. Moline's academic freedom afforded by the First Amendment, which "extends as readily to the scholar in the laboratory as to the teacher in the classroom." *In re R.J. Reynolds Co.*, 518 N.Y.S.2d 729, 734 (N.Y. Cnty. 1987) (cleaned up). Although the Second Circuit has not read *Reynolds* to adopt

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[4] During oral argument on February 8, 2023, there was discussion as to whether deceased subjects qualify as human subjects for purposes of the Common Rule. The Common Rule defines "human subject" as a "living individual." 45 C.F.R. § 46.102(e)(1). This definition, however, is wholly irrelevant as to § 46.111(a)(7), which expressly protects "subjects" not "human subjects." *See Loughrin v. United States*, 573 U.S. 351, 358 (2014) ("We have often noted that when Congress includes particular language in one section of a statute but omits it in another . . . this Court presumes that Congress intended a difference in meaning.") (cleaned up). Accordingly, the court in *Bell* erred in finding the regulation did not protect the confidentiality of Mrs. Bell's identity because she was deceased. 2022 U.S. Dist. LEXIS, at *32.

[5] A covered entity is required to comply with the Privacy Rule's disclosure requirements "with respect to the protected health information of a deceased individual **for a period of 50 years following the death of the individual**." 45 C.F.R. § 502(f).

academic freedom as a legal privilege, it has recognized the possibility that the *Reynolds* Court "regarded the scholar's interest in his research data as . . . a factor to be taken into account in weighing the burdens of production . . . ." *In re American Tobacco Co.*, 840 F.2d 1520, 1528 (2d Cir. 1989).

Finally, compliance with the subpoena would make valuable research like Dr. Moline's impossible. The JOEM, like all journals that adhere to the ethical policies put forth by the Committee on Publication Ethics (COPE) and the International Committee on Medical Journal Editors (ICMJE),[6] generally require patient consent (or a recognized exception) and IRB approval. IRB approval is predicated upon an investigator's compliance with the Common Rule and HIPAA. Anonymity is foundational to those statutory and regulatory schemes. If the ability of a investigator to preserve the anonymity of her subjects is called into question whenever an expert relies upon the research in litigation, neither IRBs nor learned journals will have confidence that their statutory, regulatory and ethical requirements will be maintained. As a result, important research will not be approved or published.

Dr. Moline's interests in non-disclosure far outweigh the Subpoenaing Defendants' expressed need for disclosure. The Subpoenaing Defendants already have ample ammunition to attack the Article's conclusion that mesothelioma "may be attributable" to contaminated powder usage and its support for Dr. Moline's conclusions as an expert witness. As Judge Miller in the Eastern District of Virginia has already found, the identities of her research subjects "would be minimally beneficial to AII in the Gref litigation." (ECF No. 306-1, p7.) Courts have consistently protected the anonymity of research subjects in cosmetic-talc cases except where they were parties to the litigation and deceased. (ECF No. 306-1 (12/23/2022 E.D. Va. Order) (quashing subpoena issued to Peninsula Pathology Associates seeking, *inter alia*, documents relating to article co-authored by Dr. Theresa S. Emory and underlying study); ECF No. 265-5. 39:17-40:7 (trial transcript excerpt in *Fisher v. Am. Int'l Indus.*, No. 1900087 (Pa. C.P. Oct. 13, 2022) (overruling objection as to responsiveness as to Dr. Moline's testimony that she does not disclose the names of individuals, which is standard medical practice); *Bell,* 2022 U.S. Dist. LEXIS 199180 (granting AII's motion to lift protective order as to the spreadsheet revealing the identity of Mrs. Bell, who is deceased and a party to that litigation, but left redacted the identities of the other research subjects); ECF No. 265-4, p11, 220:16-221:5 (bench ruling in *Johnson/Lashley v. Am. Int'l Indus.*, Nos. MID-L-006651-16 and MID-L-007336-16 (N.J. Super. Ct. Law Div. Mar. 11, 2020) (sustaining objection to question "asking Dr. Moline to testify as to whether this person is that person" because question was inappropriate).

That the subjects may have executed HIPAA authorizations permitting disclosure of their medical records in the specific litigation in which they were plaintiffs does not suggest that they were opening themselves and their family members to scrutiny and discovery in every cosmetic-

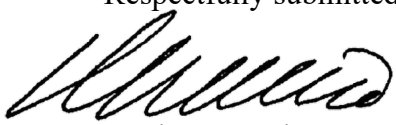
[6] https://journals.lww.com/joem/Pages/editoriallegalethicalpolicies.aspx

talc case in which an expert relied on the Article. If that were the law, the *Bell* Court would have ordered the disclosure of the identities of all the other subjects rather than just Mrs. Bell.

For the reasons set forth above and in Northwell's submissions, Dr. Moline respectfully requests that the Court quash the Subpoenaing Defendants' subpoenas seeking the disclosure of the spreadsheet identifying the subjects of her Study.

Thank you for your consideration of this submission.

Respectfully submitted,



Kevin H. Marino

cc: All counsel of record